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(54) Title: BIOABSORBABLE GLASS FIBERS FOR USE IN THE REINFORCEMENT OF BIOABSORBABLE POLYMERS FOR BONE FIXATION DEVICES AND ARTIFICIAL LIGAMENTS (57) Abstract A spun or drawn glass fiber for use in the area of medical implants, and particularly as a reinforcement for bioabsorbable polymeric orthopedic and dental implants. The glass fiber is bioabsorbable and has sufficient tensile strength and elasticity to be used as a reinforcement. It is made up of 5-50% calcium oxide (CaO), 50-95% phosphorous pentoxide (P ₂ O ₅), 0-5% calcium fluoride (CaF ₂), 0-5% water (H ₂ O), and 0-10% XO wherein X is either a single magnesium, zinc or strontium ion or two sodium, potassium, lithium, or aluminum ions and when X is aluminum the O represents three oxygen ions.		

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**BIOABSORBABLE GLASS FIBERS FOR USE IN THE
REINFORCEMENT OF BIOABSORBABLE POLYMERS FOR
BONE FIXATION DEVICES AND ARTIFICIAL LIGAMENTS**

Background of the Invention

5 The present invention relates to biocompatible
and bioabsorbable glass fibers for use in the area of
medical implants, particularly orthopaedic and dental
implants. More particularly, it relates to spun or drawn
fibers containing primarily calcium oxide (CaO) and phos-
10 phorous pentoxide (P_2O_5) which may be used as a rein-
forcement for resorbable polymeric bone plates and artifi-
cial ligaments.

 Many different materials have been used in the
area of orthopaedic and dental implant devices. For
15 example, various metals have been used as internal fixation
devices, the most common being compression plates, rods or
pins. Today the vast majority of these devices are made
up of stainless steel or titanium. They are used to hold
fractured pieces of long bones in correct alignment and to
20 minimize movement until a satisfactory union can take
place by natural bone fracture healing processes.

 This technique can provide quite satisfactory
results; however, several problems can occur due to large
differences in the modulus of elasticity of the bone and
25 metal which usually results in the need for a second
operation to remove the device. Also, for reasons not
completely understood, some individuals do not tolerate
the metal and the bone, or surrounding soft tissue, has an
inflammatory response to the metal.

30 The problem of differing elastic modulus between
the bone and metal plate and the need for a second opera-
tion can be, in some instances, directly related. In many
cases, the person receiving the implant does not have the

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5 implant removed, either due to their own neglect or the
surgeons. Even if a satisfactory bone union takes place,
the large difference in the strength and modulus will
actually result in a deterioration of the bone in the
vicinity of the metal plate. If the condition is allowed
to persist, severe pain and/or refracturing of the bone
can occur. Also, if the plate is removed, the underlying
healed bone (callus) is usually not well organized. That
is, the composite structure of the bone has not aligned
10 itself such that it has maximum strength along the direc-
tion (axis) of highest stress, which is the natural
behavior of healthy mature bone. This can best take place
if the stresses placed upon the bone are gradual, allowing
the bone sufficient time to reorganize.

15 A similar problem exists in the attempted repair
of torn, or partially torn ligaments or tendons. Ligaments
are composed of interwoven strands of collagen fibers very
much like hemp rope. When these fibers are broken, they
will, if properly stabilized and the blood supply is
adequate, repair themselves. In a manner similar to bone,
20 the collagen fibers do not realign themselves along lines
of maximum stress if the stresses are being distributed
over a permanently placed artificial support, such as
metal wires. They remain in a disorganized mass, like
25 scar tissue, with a much reduced strength when compared to
normal ligamentous material. If the supporting artificial
material is surgically removed, if that is even possible,
there is great danger of the patient suddenly applying
stress to the ligament that is too high for it to withstand
30 and further damage will occur.

For this reason, it has been proposed that a
biocompatible composition be used in the repair or replace-
ment of human body parts such as ligaments, tendons and

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bones. Thus, Alexander et al. in U.S. Patents No. 4,329,743 and 4,411,027 disclose using a composite of a bioabsorbable polymer (polylactic acid) on a substrate of a plurality of carbon fibers. See also U.S. patent 4,141,087, 4,140,678 and 4,052,988 which disclose various bioabsorbable synthetic polymers for use as permanent sutures, artificial ligaments and bone plates. However, while the polymer of Alexander et al. is bioabsorbable, the carbon fiber reinforcement is not. Since 30-60% of the bone plates and artificial ligaments of Alexander et al. are made up of the carbon fibers, the problem of bioincompatibility remains due to their being stiff and non-bioabsorbable.

It is also known that bioabsorbable ceramic materials may be used as medical implants. See, for example, U.S. patent 4,218,355 (assigned to the same assignee as the present invention), which discloses use of an aluminum oxide/calcium oxide/phosphorous pentoxide porous ceramic material as a carrier for controlled release of proteins, polypeptide hormones and other substances. It is also known that this type of ceramic composition may be used as a bioabsorbable bone graft material. See also, U.S. Patent No. 4,155,124, which discloses a burnt ceramic bone implant, and the IADR Abstracts in the March 1982 issue of the Journal of Dental Research, various ones of which disclose work with biodegradable ceramic materials.

Despite the recent efforts to develop a bioabsorbable composition or composite which may be used as an orthopaedic and dental implant, much work remains to be done. The bioabsorbable synthetic polymers do not by themselves have sufficient structural strength to be used alone as an implant and the porous ceramic materials tend

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to be too rigid and brittle. Accordingly, the need exists for an improved biocompatible and bioabsorbable material for use in the area of orthopaedic and dental implants, and particularly a material which can be used to reinforce existing bioabsorbable synthetic polymers to form a composite suitable for that purpose.

Summary of the Invention

The present invention meets that need by providing a reinforcement for bioabsorbable polymeric orthopaedic and dental implants, such as bone plates and artificial ligaments. The reinforcement is a spun or drawn glass fiber having the required tensile strength and resorption properties. As such, the glass fiber is able to reinforce a polymer matrix as the resorbable polymer and the glass fiber is gradually being reduced in strength and elastic modulus (through slow, steady bioabsorption), while allowing the bone or ligament to gradually reorganize and increase to normal strength and modulus. After a reasonable period of time (approximately one year), the implant, including the glass fiber reinforcement, is completely consumed in the body causing no inflammatory, carcinogenic, or toxic reactions. This is because of the bioabsorbable nature of the glass fiber reinforcement.

The spun or drawn glass fiber of the present invention is basically made up of a binary mixture of calcium oxide (CaO) and phosphorous pentoxide (P_2O_5); although, other ingredients such as calcium fluoride (CaF_2), water (H_2O), and other oxides containing cations such as magnesium, zinc, strontium, sodium, potassium, lithium and aluminum may also be incorporated in small amounts. In terms of the binary mixture, the preferred Ca:P mole ratio is 0.25 to 0.33. Preferably, the

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glass comprises by weight 5-50% CaO, 50-95% P₂O₅, 0-5% CaF₂, 0-5% H₂O, and 0-10% XO, wherein X is a single magnesium, zinc or strontium ion or two sodium, potassium, lithium or aluminum ions and O is a single oxygen ion except when X is aluminum, in which case it is three oxygen ions. More preferably, the calcium oxide (CaO) is present by weight in the amount of 15-25%; the phosphorous pentoxide (P₂O₅) is present by weight in the amount of 65-90%; and either calcium fluoride (CaF₂) or water (H₂O) is present by weight in the amount of 0.1-4%.

The glass composition which is spun or drawn into the glass fiber reinforcement should obviously have good melting and fiber drawing characteristics. It should be capable of being drawn into fibers having a diameter between 1 to 100 microns, preferably 5 to 25 microns, and most preferably 8 to 15 microns, without crystallization during fiber drawing. Likewise, the drawn fibers should have a good tensile strength and modulus of elasticity.

Finally, the drawn fiber should be bioabsorbable, i.e., it should dissolve in vitro in a static solution of buffered saline in approximately 30 to 40 days, and should absorb in vivo, as implanted, slowly over six months to one year. In this manner, the glass fiber reinforcement of the present invention is able to gradually loose strength and safely absorb in the body as the strength of the bone, ligament, tendon or other body part is gradually and effectively increased. The glass fiber of the present invention, appropriately coated with a thin protective coating, may also be used by itself (and not necessarily as a reinforcement) as a bioabsorbable suture, lashing, or other type of medical implant.

Accordingly, it is an object of the present invention to provide a spun or drawn glass fiber which is

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bioabsorbable and useful in the area of medical implants, particularly orthopaedic and dental implants.

These and other objects of the invention will be apparent from the following description and the appended claims.

Detailed Description of the Preferred Embodiments

The glass composition used to produce the glass fiber reinforcement of the present invention as mentioned, preferably contains by weight 5-50%, most preferably 15-25%, calcium oxide (CaO) and 50-95%, most preferably 65-90%, phosphorous pentoxide (P_2O_5). The preferred atomic ratio for calcium:phosphorous is about 0.25 to 0.33. Thus, in its basic form, the glass composition is a binary mixture of calcium oxide and phosphorous pentoxide in the given ranges and having the preferred Ca:P mole ratio. However, usually other constituents are also present. It may contain from 0-5% and preferably 0.1-4% by weight calcium fluoride (CaF_2) or water (H_2O) or one or more of other oxides such as magnesium oxide (MgO), zinc oxide (ZnO), strontium oxide (SrO), sodium oxide (Na_2O), potassium oxide (K_2O), or lithium oxide (Li_2O), or aluminum oxide (Al_2O_3).

It is important, however, that any added fluoride or oxide not result in development of undue crystallinity in the glass composition during fiber drawing. That is, the glass composition must be readily melted to a homogeneous liquid having melt viscosity suitable for fiber drawing purposes. Typically, these compositions have a melt viscosity of about 1000 to 10,000 poise at the drawing temperature. The drawing temperature is preferably at least about 100°C above the liquidus temperature of the

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composition. It should be capable of being spun or drawn to a diameter of between 1 to 100 microns, preferably between 5 to 25 microns, and most preferably 8 to 15 microns using ordinary techniques. And it should have good tensile strength and modulus of elasticity so as to not be too rigid and brittle as are many ceramic materials.

In terms of tensile strength, the fiber should have a tensile strength ranging from 200 to 550 megapascals (MPa) and 30 to 200 thousand pounds per square inch (Ksi), i.e., 30,000 to 80,000 psi. The preferred range for Young's modulus is 2×10^6 to 7×10^6 psi.

Also as mentioned, the fiber should be bioabsorbable so that upon implanting it will gradually resorb over a six-month to one-year period. A key to this is the fact that the chemical composition of the glass reinforcement fibers of the present invention is similar to that of fluoro and hydroxy apatite minerals which closely resemble the chemistry of bone minerals. The chemical formulas for the fluoro and hydroxy apatites are $\text{Ca}_{10}\text{P}_6\text{O}_{24}\text{F}_2$ and $\text{Ca}_{10}\text{P}_6\text{O}_{24}(\text{OH})_2$, respectively. If these formulas are expressed as oxide and fluoride weight percent, the fluoro apatite would be expressed as CaO - 50.01%, CaF_2 - 7.74%, and P_2O_5 - 42.25%. Similarly, the hydroxy apatite would be expressed as CaO - 54.91%, H_2O - 3.33%, and P_2O_5 - 41.75%. These two minerals in the crystalline state can be chemically synthesized in the laboratory. These chemically synthesized apatites in powder or aggregate form are available in the market for bio-applications.

For present purposes, a material in the fibrous form is, however, being sought. The fabrication of fibers from the two crystalline apatite minerals is difficult and

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to our knowledge has not before been used to produce a glass fiber reinforcement for use in the area of medical implants. However, if these two minerals can be produced in the vitreous or amorphous state and a desirable viscosity range is obtained, fibers could easily be drawn. The present invention relates to the development of glass compositions for fiber making from the $\text{CaO-CaF}_2\text{-P}_2\text{O}_5$ and $\text{CaO-H}_2\text{O-P}_2\text{O}_5$ system.

Example I

Analytical grade powders of CaO , CaF_2 , and P_2O_5 were weighed to obtain a predetermined ratio and were then thoroughly mixed. The mixed batches were melted in a platinum crucible. The melting temperature and time depended upon the composition. The melting temperature ranged from 800°C to 1400°C , and the melting time varied from 15 minutes to 6 hours. The objective in all the melting experiments was to obtain a clear and homogeneous melt from which fibers could be drawn. After melting, the crucible was transferred to another furnace which was maintained at a lower temperature in order to maintain a proper viscosity for fiber drawing. The fibers were then drawn manually and the suitability of the various melts for fiber drawing was evaluated. The results are set forth in Table I.

TABLE I

COMPOSITIONS IN WEIGHT PERCENT

Compositions:	<u>#1</u>	<u>#2</u>	<u>#3</u>	<u>#4</u>
CaO	50.01	48.00	40.00	23.00
CaF ₂	7.74	7.75	6.00	0.00
P ₂ O ₅	42.25	44.25	54.00	77.00

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Remarks:

Composition #1: Highly refractory composition. Melting at 1400°C produced insignificant amount of liquid or glass phase.

5 Composition #2: Melted at 1400°C. A clear and homogeneous liquid was produced. However, fibers would not be drawn; the glass crystallized spontaneously during fiber drawing.

10 Composition #3: The composition melted to a homogeneous and clear liquid. Improved melt viscosity, but still crystallized during fiber drawing.

Composition #4: Melted at 900°C. Clear and homogeneous glass obtained. The composition exhibited excellent properties for fiber drawing.

15 As can be seen from Table I, composition #1 corresponds to the fluoro apatite mineral. This composition is highly refractory and difficult to melt. By reducing CaO and increasing P₂O₅ contents, the meltability was improved as in composition #2; however, it crystallized during fiber drawing. By further decreasing
20 CaO and CaF₂, and increasing P₂O₅ as in compositions #3 and #4, meltability as well as fiber drawing characteristics were improved. Composition #4 exhibited the most desirable melting and fiber drawing characteristics. Several hundred grams of glass and fibers were produced
25 from composition #4 for use in biocompatibility evaluations.

30 Glass fibers drawn from composition #4 were drawn to diameters ranging from 0.0024-0.0045 inches. Some of these were tested for tensile strength and elasticity. The average tensile strength (five fibers tested) was 37,100 psi. The average Young's modulus was 2.4×10^6 psi.

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Some of the fibers drawn from composition #4 were placed in a static solution of buffered saline and were found to go into solution after approximately 40 days. Others of the fibers drawn from composition were implanted in rats and rabbits as single fibers and as fibers coated with a solution of polylactic acid. The results after 4, 12 and 24 week implant periods showed that the fibers slowly degraded and were consumed in the physiological environment, causing no inflammation or other untoward effects that could be ascertained by standard histological examination.

Example II

Eighty-five (85) grams of bulk glass was prepared from, by weight, 20% calcium oxide (CaO), 77% phosphorous pentoxide (P_2O_5), and 3% water (H_2O). The entire 85 grams was drawn into a continuous fiber that ranged in diameter from 8 to 12 microns.

Static dissolution studies performed on some of the fibers showed them to be absorbable in vitro (in buffered saline) and others of fibers from the same batch were implanted (uncoated) in the back muscles of rabbits. The histology indicated that these fibers dissolved in vivo and were consumed in approximately 6 months.

Others of the fibers were tested for mechanical properties. The results of those studies are set forth in Table II. As shown in Table II, ultimate tensile strength was determined from twenty-two mounted test fibers. A total of twenty-six fibers were mounted on 35 mm slide mounts using the technique discussed above. The diameter of each mounted fiber was determined by direct measurement on a micro-hardness tester. Specimens #4 and #26 were

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observed to be twisted double fiber mounts while measuring fiber diameters and therefore were not tested. Specimen #1 was broken during the cutting and clipping of the slide mount immediately prior to testing. Specimen #24 failed in the wax at the slide mount and was deemed an invalid test. The results for the remaining test specimens are compiled in Table II.

TABLE II

GLASS FIBER TENSILE TEST RESULTS

	SPECIMEN NUMBER	DIAMETER (microns)	ULTIMATE TENSILE STRENGTH	
			MPa	ksi
	2	12.3	362.4	52.6
	3	11.2	402.3	58.3
	5	14.1	317.9	46.1
15	6	13.6	357.9	51.9
	7	12.0	376.4	54.6
	8	13.1	414.9	60.2
	9	12.4	320.9	46.5
	10	12.6	360.3	52.3
20	11	13.6	393.8	42.6
	12	11.6	339.7	49.3
	13	12.5	372.5	54.0
	14	12.8	301.9	43.8
	15	10.8	463.7	67.2
25	16	11.1	472.5	68.5
	17	12.8	521.5	75.6
	18	13.2	414.3	60.1
	19	11.5	410.8	59.6
	20	12.0	459.7	66.7
30	21	11.2	450.1	65.3
	22	10.7	512.8	74.4
	23	13.2	448.0	65.0
	25	13.5	390.6	56.7
	\bar{x}	12.4	398.4	57.8
35	s	1.0	65.2	9.5

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5 While the product herein described constitutes preferred embodiments of the invention, it is to be understood that the invention is not limited to this precise product, and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

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1. A spun or drawn glass fiber, which is bioabsorbable and useful in the area of medical implants, comprising calcium oxide (CaO) and phosphorous pentoxide (P_2O_5).

2. The glass fiber of claim 1 wherein said fiber has a diameter in the range of 1-100 microns.

3. The glass fiber of claim 2 wherein said fiber has a diameter in the range of 5-25 microns.

4. The glass fiber of claim 2 wherein said glass fiber comprises by weight:

CaO	5-50%
P_2O_5	50-95%
CaF_2	0-5%
H_2O	0-5%
XO	0-10%

wherein X is selected from the group consisting of a single magnesium, zinc or strontium ion and two sodium, potassium, lithium or aluminum ions, and when X is aluminum O is three oxygen ions.

5. The glass fiber of claim 4 wherein said calcium oxide (CaO) is present by weight in the amount of 15-25% and said phosphorous pentoxide (P_2O_5) is present by weight in the amount of 65-90%.

6. The glass fiber of claim 4 wherein said calcium fluoride (CaF_2) is present by weight in the amount of 0.1-4%.

7. The glass fiber of claim 4 wherein said water (H_2O) is present by weight in the amount of 0.1-4%.

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8. The glass fiber of claim 1 wherein the Ca:P atomic ratio is about 0.25 to 0.33.

9. A reinforcement for a bioabsorbable polymeric orthopaedic or dental implant comprising a drawn or spun glass fiber made up of by weight of:

CaO	5-50%
P ₂ O ₅	50-95%
CaF ₂	0-5%
H ₂ O	0-5%
XO	0-10%

wherein X is selected from the group consisting of a single magnesium, zinc or strontium ion and two sodium, potassium, lithium or aluminum ions, and when X is aluminum O is three oxygen ions.

10. The reinforcement of claim 9 wherein said fiber has a diameter in the range of 5 to 25 microns.

11. The reinforcement of claim 10 wherein said fiber has a diameter in the range of 8 to 15 microns.

12. The reinforcement of claim 11 wherein said fiber has a tensile strength of 30,000 to 200,000 psi and a Young's modulus of 2×10^6 to 7×10^6 psi.

13. The reinforcement of claim 12 wherein said glass fiber comprises by weight:

CaO	15-25%,
P ₂ O ₅	65-90%, and
H ₂ O	0.1-4%.

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14. The reinforcement of claim 9 wherein the Ca:P atomic ratio is 0.25 to 0.33.

15. The glass fiber of claim 1 wherein said fiber has a melt viscosity of 1000 to 10,000 poise at its drawing temperature.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US86/00288

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ³

According to International Patent Classification (IPC) or to both National Classification and IPC

INT. CL.4 A61F 2/08

U.S. CL. 623/16; 128/92C; 106/35; 433/201; 623/11, 118

II. FIELDS SEARCHED

Minimum Documentation Searched ⁴

Classification System

Classification Symbols

U.S.

623/16; 128/92C; 106/35; 433/201; 623/11, 118

Documentation Searched other than Minimum Documentation
to the Extent that such Documents are Included in the Fields Searched ⁵

III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴

Category [*]	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸
A	US, A, 4,052,988 PUBLISHED 11 OCTOBER 1977 DODDI ET AL	1-15
A	US, A, 4,140,678 PUBLISHED 20 FEBRUARY 1979 SHALABY ET AL	1-15
A	US, A, 4,141,087 PUBLISHED 27 FEBRUARY 1979 SHALABY ET AL	1-15
A	US, A, 4,155,124 PUBLISHED 22 MAY 1979 KAWAHARA ET AL	1-15
A	US, A, 4,218,255 PUBLISHED 19 AUGUST 1980 BAJPAI ET AL	1-15
A	US, A, 4,308,064 PUBLISHED 29 DECEMBER 1981 TAKAMI ET AL	1-15
A	US, A, 4,329,743 PUBLISHED 18 MAY 1982 ALEXANDER ET AL	1-15
A	US, A, 4,411,027 PUBLISHED 25 OCTOBER 1983 ALEXANDER ET AL	1-15

^{*} Special categories of cited documents: ¹⁵

"A" document defining the general state of the art which is not considered to be of particular relevance

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IV. CERTIFICATION

Date of the Actual Completion of the International Search ²

19 APRIL 1986

International Searching Authority ¹

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Date of Mailing of this International Search Report ²

19 MAY 1986

Signature of Authorized Officer ²⁰

Marvin L. Moore